

**Food and Drug Administration
Center for Drug Evaluation and Research**

**Arthritis Advisory Committee
Gaithersburg Holiday Inn, 2 Montgomery Village Avenue, Gaithersburg, MD**

**Agenda
August 16, 2001**

BLA STN 103950 Kineret™, (anakinra), Amgen, Inc.

- 8:00 Call to Order and Introductions:** E. Nigel Harris, M.D., Acting Chair
Meeting Statement: Kathleen Reedy, Executive Secretary
Welcome and Introduction: William Schwieterman, M.D. , Branch Chief
Division of Clinical Trial Design and Analysis
Office of Therapeutics Research and Review, CBER
- 8:15 Amgen Inc. Presentation:**
Overview: Roger Perlmutter, MD, PhD, Amgen,
Executive Vice President, Research and Development
Clinical Experience: Moraye Bear, MA, MS, Amgen, Director, Clinical Research
Pirow Bekker, MD, PhD, Amgen, Senior Director, Clinical Research
Concluding Statements: Stanley B. Cohen, MD
Medical Director, Radiant Research, Dallas, Texas
Associate Director, St. Paul Medical Center, Dallas, Texas
President, ACR Research and Education Foundation
- 9:45 Break**
- 10:00 FDA, CBER Presentation**
Overview and Introduction: Raymond P. Donnelly, Ph.D., Senior Investigator
Division of Therapeutic Proteins
Efficacy and Safety: Jeffrey N. Siegel, M.D., Medical Reviewer
Division of Clinical Trial Design and Analysis
Office of Therapeutics Research and Review
- 11:00 Open Public Hearing**
- 11:30 Lunch**
- 12:30 Discussion and Questions**
- Break**
- 4:30 Summary**
- 5:00 Adjourn**